U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125771/0

FILING NOTIFICATION
August 26, 2022

Bioverativ Therapeutics, Inc.
Attention: HeiJen Sun, PhD
55 Corporate Drive
Bridgewater, NJ 08807

Dear Dr. Sun:

Please refer to your final portion of your rolling Biologics License Application (BLA) received June 30, 2022, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein.

We also refer to your amendments for the initial portions of your rolling BLA received May 12, 2022.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Under 21 CFR 601.2(a), we have filed your application today. The review classification for this application is **Priority**, the review goal date is February 28, 2023. This acknowledgment of filing does not mean that we have issued a license, nor does it represent any evaluation of the adequacy of the data submitted.

This application is also subject to the provisions of "the Program" under the Prescription Drug User Fee Act (PDUFA). Refer to https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserfee/ucm446608.htm.

We are reviewing your application according to the processes described in the guidance for industry and review staff *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-review-management-principles-and-practices-new-drug-applications-and-biologics-license. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). We plan to hold our internal mid-cycle review meeting on October 12, 2022. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing requirement/commitment requests by January 27, 2023.

We are not currently planning to hold an advisory committee meeting to discuss this application.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the indication you are requesting has orphan drug designation, PREA does not apply.

If you have any questions, please contact the Regulatory Project Manager, Niloofar Kennedy, at (240) 695-2400 or by email at niloofar.kennedy@fda.hhs.gov.

Sincerely,

Ramani Sista, PhD
Director
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research